



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

December 4, 1991

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP)
Regulation

GLP Regulations Advisory No. 38

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at FTS 398-8333 (703) 308-8333.

Attachment

cc: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear

This is in reply to your letter of October 29, 1991 in which you requested clarification regarding the Good Laboratory Practice Standards (GLPS). Specifically, you asked whether the GLPS allow responsibility for archive maintenance to be assigned to members of a testing facility's quality assurance unit (QAU). You are interested in assigning the archive responsibilities to the Quality Assurance Officer of one of your satellite facilities.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) GLPS state at 40 CFR 160.190(c) that "...an individual shall be identified as responsible for the archives. n As you have correctly determined, the regulations do not prohibit assignment of archive responsibilities to a member of the QAU. Please note, however, that the regulations are clear that a single individual must be identified as responsible for archives. If you were to generically designate an organizational subunit (i.e., the QAU) as responsible for archives you would not meet this requirement.

If you have any questions concerning this response, please contact Steve Howie of my staff at (703) 308-8290.

Sincerely yours,

/s/ John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

cc: David Dull
GLP File